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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Koji TESHIMA et al.

: Docket No. 2004\_1514A

Serial No. 10/508,339

Filed September 20, 2004

REMEDY FOR SLEEP DISTURBANCE

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEES FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application  
PCT/\_\_\_\_\_; and/or
- ☐ each reference previously cited in prior parent application Serial No.  
\_\_\_\_\_.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and**

**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☒ a full or partial English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☒ the concise explanation contained in the specification of the present application at page 1,
  - d. ☒ the concise explanation set forth in the attached English language abstract,
  - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Koji TESHIMA et al.

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December 20, 2004

## INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY DOCKET NO.  
2004\_1514ASERIAL NO.  
508,339LIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)APPLICANT  
Koichi TESHIMA et al.

Date Submitted to PTO: December 20, 2004

FILING DATE  
September 20, 2004

GROUP

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6,172,067	1/2001	Ito et al.			
	AB	6,642,247	11/2003	Adam et al.			
	AG	6,172,075	8/2001	Adam et al.			
	AD	6,277,991	8/2001	Hohlweg et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AE	2000-53686	2/2000	JP			Abstract
	AF	00/14067	3/2000	WO			
	AG	00/31061	6/2000	WO			Abstract
	AH	2001-58991	3/2001	JP			Abstract
	AI	00/08013	2/2000	WO			Corresponds to AA
	AJ	02/10169	2/2002	WO			Corresponds to DB,DC

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	Laura McAtee et al., "High-Affinity, Non-Peptide Agonists for the ORL1 (Orphanin FQ/Nociceptin) Receptor". CHEMTRACTS - ORGANIC CHEMISTRY, 14(9), pages 513-517, 2001.
	AL	James Bunzow et al., "Molecular cloning and tissue distribution of a putative member of the rat opioid receptor gene family that is not a $\mu$ , $\delta$ or $\kappa$ opioid receptor type". FEBS Lett. vol. 347, pages 284-288, 1994.
	AM	Catherine Mollereau et al., "ORL1, a novel member of the opioid receptor family". FEBS Lett. vol. 341, pages 33-38, 1994.
	AN	Jean-Claude Meunier, "Nociceptin/orphanin FQ and the opioid receptor-like ORL1 receptor". European Journal of Pharmacology vol. 340, pages 1-15, 1997.
	AO	Jeffrey S. Mogil et al., "The Molecular and Behavioral Pharmacology of the Orphanin FQ/Nociceptin Peptide and Receptor Family". Pharmacological Reviews, vol. 53, No. 3, pages 381-415, 2001.
	AP	Jean-Claude Meunier et al., "Isolation and structure of the endogenous agonist of opioid receptor-like ORL1 receptor". Letters to Nature, vol. 377, pages 532-535. 1995.

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLA SS	FILING DATE IF APPROPRIATE
	BA	6,043,366	3/2000	Adam et al.			

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLA SS	TRANSLATION YES NO
	BB	00/06545	2/2000	WO			
	BC	02/26714	4/2002	WO			Abstract
	BD	10-212290	8/1998	JP			Corresponds to CA
	BE	1 122 257	8/2001	EP			Corresponds to DE
	BE	2001-39974	2/2001	JP			Corresponds to CC

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	BG	John Sandin et al., "SHORT COMMUNICATION: Nociceptin/Orphanin FQ Microinjected into Hippocampus Impairs Spatial Learning in Rats". European Journal of Neuroscience, vol. 9, pages 194-197, 1997.
	BH	Toshiya Manabe et al., "Facilitation of long-term potentiation and memory in mice lacking nociceptin receptors". Nature, vol. 394, pages 577-581, 1998.
	BI	Francois Jenck et al., "Orphanin FQ acts as an anxiolytic to attenuate behavioral responses to stress". Proc. Natl. Acad. Sci., vol. 94, pages 14854-14858, 1997.
	BL	Anja Koster et al., "Targeted disruption of the orphanin FQ/nociceptin gene increases stress susceptibility and impairs stress adaptation in mice". Proc. Natl. Acad. Sci., vol. 96, pages 10444-10449, 1999.
	BK	Molecular Medicine, vol. 34, no. 3, pages 355-365, 1997 and partial English translation.
	BL	Charles N. Allen, "Orphanin-FQ/Nociceptin (OFQ/N) Modulates the Activity of Suprachiasmatic Nucleus Neurons". The Journal of Neuroscience, vol. 19(6), pages 2152-2160, 1999.
	BM	Rainer K. Reinscheid et al., "Orphanin FQ: A Neuropeptide That Activates an Opioidlike G Protein-Coupled Receptor". Science, vol. 270, pages 792-794, 1995.
	BN	Girolamo Calo et al., "Pharmacology of nociceptin and its receptor: a novel therapeutic target". British Journal of Pharmacology, vol. 129, pages 1261-1283, 2000.

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	CC	6,340,681	1/2002	Ito			
	CD	6,423,725	7/2002	Ito et al.			
	CE	6,465,478	10/2002	Ito et al.			
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	CH	0 997 464	5/2000	EP			Corresponds to CE	
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	CJ	98/54168	12/1998	WO			Corresponds to CF	
	CK	03/000677	1/2003	WO			Corresponds to DF,DG	
	CL	02/085354	10/2002	WO			Corresponds to DK	
	CM	02/085355	10/2002	WO			Corresponds to CG,DL	
	CN	02/085361	10/2002	WO			Corresponds to DM	
	CO	02/085291	10/2002	WO			Corresponds to DJ	
	CP	01/39775	6/2001	WO			Corresponds to DI	
	CQ	99/48492	9/1999	WO			Corresponds to DA,DO	
	CR	00/27815	5/2000	WO			Corresponds to DN	
	CS	99/59997	11/1999	WO			Corresponds to AD	

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	DR	99/29696	6/1999	WO			Corresponds to CB	
	DS	99/36421	7/1999	WO			Corresponds to CD	

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